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I hereby certify that this correspondence is being facsimile transmitted to the Patent and Trademark Office, Facsimile No. (703) 872-9306, on the date shown below.  
Dated: June 24, 2005      Signature: *Barbara M. Weatherly*  
(Barbara M. Weatherly)

Patent  
Docket No. 252312007400

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:  
Matthew D. LINNIK et al.

Examiner: C. Qian

Serial No.: 09/724,822

Group Art Unit: 1636

Filing Date: November 28, 2000

For: METHODS OF TREATING LUPUS  
BASED ON ANTIBODY AFFINITY  
AND SCREENING METHODS AND  
COMPOSITIONS FOR USE THEREOFSUPPLEMENTAL INFORMATION DISCLOSURE  
STATEMENT UNDER 37 C.F.R. § 1.97 & 1.98MS PETITION  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. § 1.97 and § 1.98, Applicants submit for consideration in the above-identified application the document listed on the attached Form PTO/SB/08a/b. A copy of the document is also submitted herewith. The Examiner is requested to make this document of record.

This Supplemental Information Disclosure Statement is submitted:

- ☐ With the application; accordingly, no fee or separate requirements are required.
- ☒ Before the mailing of a first Office Action after the filing of a Request for Continued Examination under § 1.114.

Application Serial No. 09/724,822

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- ☐ Within three months of the application filing date or before mailing of a first Office Action on the merits; accordingly, no fee or separate requirements are required. However, if applicable, a certification under 37 C.F.R. § 1.97 (e)(1) has been provided.
- ☐ After receipt of a first Office Action on the merits but before mailing of a final Office Action or Notice of Allowance.
- ☐ A fee is required. A check in the amount of \_\_ is enclosed.
- ☐ A fee is required. Accordingly, a Fee Transmittal form (PTO/SB/17) is attached to this submission in duplicate.
- ☐ A Certification under 37 C.F.R. § 1.97(e) is provided above; accordingly, no fee is believed to be due.
- ☐ After mailing of a final Office Action or Notice of Allowance, but before payment of the issue fee.
- ☐ A Certification under 37 C.F.R. § 1.97(e) is provided above and a check in the amount of \_\_ is enclosed.
- ☐ A Certification under 37 C.F.R. § 1.97(e) is provided above and a Fee Transmittal form (PTO/SB/17 is attached to this submission in duplicate.)

Submitted herein is information from the regulatory agency United States Food and Drug Administration (FDA) dated October 13, 2004, addressing clinical trial data regarding a response associated with treatment relating to that disclosed and claimed in the instant application.

Applicants would appreciate the Examiner initialing and returning the Form PTO/SB/08a/b, indicating that the information has been considered and made of record herein.

The information contained in this Supplemental Information Disclosure Statement under 37 C.F.R. § 1.97 and § 1.98 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

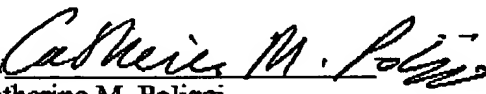
Application Serial No. 09/724,822

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In the unlikely event that the transmittal form is separated from this document and the Patent and Trademark Office determines that an extension and/or other relief (such as payment of a fee under 37 C.F.R. § 1.17 (p)) is required, Applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petition and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing 252312007400.

Dated: June 24, 2005

Respectfully submitted,

By 

Catherine M. Polizzi

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ALTERNATIVE TO PTO/SB/08/a/b (06-03)

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|--|---|----|---|--------------------------|-------------------|
| Substitute for form 1449/PTO   |   |    |   | <b>Complete if Known</b> |                   |
| <b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br><i>(Use as many sheets as necessary)</i> |   |    |   | Application Number       | 09/724,822        |
|  |   |    |   | Filing Date              | November 28, 2000 |
|  |   |    |   | First Named Inventor     | Matthew D. LINNIK |
|  |   |    |   | Art Unit                 | 1636              |
|  |   |    |   | Examiner Name            | C. Qian           |
| Sheet  | 1 | of | 1 | Attorney Docket Number   | 252312007400      |

| U.S. PATENT DOCUMENTS |                       |   |                                |  |   |
|-----------------------|-----------------------|---|--------------------------------|--|---|
| Examiner Initials*    | Cite No. <sup>1</sup> | Document Number<br>Number-Kind Code <sup>2</sup> (if known) | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines, Where<br>Relevant Passages or Relevant<br>Figures Appear |
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| FOREIGN PATENT DOCUMENTS |                       |  |                                |  |   |                |
|--------------------------|-----------------------|--|--------------------------------|--|---|----------------|
| Examiner Initials*       | Cite No. <sup>1</sup> | Foreign Patent Document<br>Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>2</sup> (if known) | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines,<br>Where Relevant Passages<br>or Relevant Figures Appear | T <sup>5</sup> |
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\*EXAMINER: Initial if information considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kind Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

| NON PATENT LITERATURE DOCUMENTS |                       |   |                |
|---------------------------------|-----------------------|---|----------------|
| Examiner Initials*              | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T <sup>2</sup> |
|                                 | 1.                    | Food and Drug Administration (October 13, 2004). Information from United States Food and Drug Administration, 2 pages.  |                |

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<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

|                    |  |                 |  |
|--------------------|--|-----------------|--|
| Examiner Signature |  | Date Considered |  |
|--------------------|--|-----------------|--|

pa-989828

ALTERNATIVE TO PTO/SB/08 a/b (08-03)

|  |   |    |   |                          |                   |
|--|---|----|---|--------------------------|-------------------|
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|  |   |    |   | Examiner Name            | C. Qian           |
| Sheet  | 1 | of | 1 | Attorney Docket Number   | 252312007400      |

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|-----------------------|--------------------------|---|--------------------------------|--|---|
| Examiner<br>Initials* | Cite<br>No. <sup>1</sup> | Document Number<br>Number-Kind Code <sup>2</sup> (if known) | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines, Where<br>Relevant Passages or Relevant<br>Figures Appear |
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| FOREIGN PATENT DOCUMENTS |                          |  |                                   |  |   |                |
|--------------------------|--------------------------|--|-----------------------------------|--|---|----------------|
| Examiner<br>Initials*    | Cite<br>No. <sup>1</sup> | Foreign Patent Document<br>Country Code <sup>2</sup> -Number <sup>3</sup> -Kind Code <sup>2</sup> (if known) | Publication<br>Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines,<br>Where Relevant Passages<br>or Relevant Figures Appear | T <sup>4</sup> |
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| Examiner<br>Initials*           | Cite<br>No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T <sup>4</sup> |
|                                 | 1.                       | Food and Drug Administration (October 13, 2004). Information from United States Food and Drug Administration, 2 pages.  |                |

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